

NEW BRUNSWICK, NJ 08933-7003

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

FILING DATE FIRST NAMED INVENTOR ATTORNEY DOCKET NO. CONFIRMATION NO. APPLICATION NO. CRD-5055 8245 10/687,143 10/16/2003 Craig Bonsignore **EXAMINER** 27777 01/24/2006 SONNETT, KATHLEEN C PHILIP S. JOHNSON JOHNSON & JOHNSON PAPER NUMBER ART UNIT ONE JOHNSON & JOHNSON PLAZA

3731
DATE MAILED: 01/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

		ℓ	
	Application No.	Applicant(s)	
Office Action Summary	10/687,143	BONSIGNORE ET AL.	
	Examiner	Art Unit	
	Kathleen Sonnett	3731	
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply			
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).			
Status			
1) Responsive to communication(s) filed on 16 March 2003.			
2a) ☐ This action is FINAL . 2b) ☒ This	This action is FINAL . 2b)⊠ This action is non-final.		
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is			
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.			
Disposition of Claims			
4)⊠ Claim(s) <u>1-10</u> is/are pending in the application.			
4a) Of the above claim(s) is/are withdrawn from consideration.			
5) Claim(s) is/are allowed.			
6)⊠ Claim(s) <u>1-10</u> is/are rejected.			
7) Claim(s) is/are objected to.			
8) Claim(s) are subject to restriction and/or election requirement.			
Application Papers			
9) The specification is objected to by the Examiner.			
10)⊠ The drawing(s) filed on <u>16 March 2003</u> is/are: a)⊠ accepted or b)□ objected to by the Examiner.			
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).			
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).			
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.			
Priority under 35 U.S.C. § 119			
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of:			
1. Certified copies of the priority documents have been received.			
2. Certified copies of the priority documents have been received in Application No			
3. Copies of the certified copies of the priority documents have been received in this National Stage			
application from the International Bureau (PCT Rule 17.2(a)).			
* See the attached detailed Office action for a list of the certified copies not received.			
Attachment(s)			
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) Interview Summary Paper No(s)/Mail Da		
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)	5) D Notice of Informal P	atent Application (PTO-152)	
Paper No(s)/Mail Date <u>1/25</u> /05	6) Other:		

Art Unit: 3731

DETAILED ACTION

Double Patenting

- 1. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).
- 2. A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.
- 3. Claims 1-9 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-9 of copending Application No. 10/688,171. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.
- 4. Claims 1-9 are directed to the same invention as that of claims 1-9 of commonly assigned copending Application No. 10/688,171. The issue of priority under 35 U.S.C. 102(g) and possibly 35 U.S.C. 102(f) of this single invention must be resolved.
- 5. Since the U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302), the assignee is required to state which entity is the prior inventor of the conflicting subject matter. A terminal disclaimer has no effect in this situation since the basis for refusing more than one patent is priority of invention under 35 U.S.C. 102(f) or (g) and not an extension of monopoly.

Art Unit: 3731

Failure to comply with this requirement will result in a holding of abandonment of this application.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

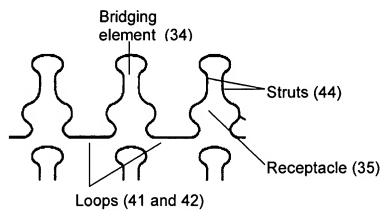
A person shall be entitled to a patent unless -

- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
- (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
- 7. Claims 1-4 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by Alt et al. (U.S. 6,251,134).
- 8. Regarding Claim 1, Alt et al. discloses a medical device with multiple, independent, self-expanding stent segments, each stent segment including a plurality of longitudinal struts (44), a plurality of loops connecting adjacent struts (41 and 42), at least one bridging element (34) and at least one receptacle (35) (Fig 3). The bridging element is configured to be releasably engaged with the receptacle on an adjacent stent segment (Fig. 3; col. 4, lines 19-50; see also the illustration following para. 12 of this office action).

Art Unit: 3731

9. Regarding Claim 2, Alt et al. discloses the medical device as stated above wherein the at least one bridging element comprises an elongate member extending from one of the plurality of loops and having a free end with a mating protrusion (Fig 3, "34").

- 10. Regarding Claim 3, Alt et al. discloses the medical device as stated above further including at least one receptacle configured as a space between adjacent longitudinal struts that defines a cavity for the elongate member and protrusion member (Fig 3, "35").
- 11. Regarding Claim 4, Alt et al. discloses the medical device as stated above wherein the cavity and the mating protrusion have a substantially oval shape (Fig 2, "34" and "35").
- 12. Regarding Claim 7, Alt et al. discloses the medical device as stated in paragraph 1, wherein the plurality of struts and the plurality of loops form a substantially S-shaped configuration (Fig 3).



13. The figure shown above has been taken from Fig. 3 of Alt et al. and labeled by the examiner in order to clarify the examiner's assignment of parts. Referring to the Figure directly above, 44 indicates parallel struts, 41 and 42 indicate loops which extends to

the receptacles on the adjacent loops, 34 indicates the bridging element, and 35 indicates a receptacle.

14. Claim 10 is rejected under 35 U.S.C. 102(b) as being anticipated by Thompson et al. (U.S. 6,623,518). Thompson et al. discloses a delivery system for a segmented, self-expanding stent comprising an outer sheath including an elongated tubular member having distal and proximal ends and an inner shaft located coaxially and slidably within the outer sheath (col. 3, lines 55-60 and col.2, lines 26-28). The shaft has a collar (27) that includes mating sections (82 and 84) for releasably securing at least a portion of the segmented, self-expanding stent (Fig 6A).

15. Claims 1-4 and 7 are further rejected under 35 U.S.C. 102(e) as being anticipated by Chew et al. (U.S. 2003/0135266).

16. Regarding Claim 1, Chew et al. discloses a medical device with multiple, independent, self-expanding stent segments, each stent segment including a plurality of longitudinal struts (54), a plurality of loops connecting adjacent struts (1,2), at least one bridging element (62) and at least one receptacle (64). The bridging element is configured to be releasably engaged with the receptacle on an adjacent stent segment (See illustration, taken from Fig. 5B, following para. 20 of this office action).

17. Regarding Claim 2, Chew et al. discloses the medical device as stated above wherein the at least one bridging element comprises an elongate member extending from one of the plurality of loops and having a free end with a mating protrusion (Fig 5B, "62").

Application/Control Number: 10/687,143

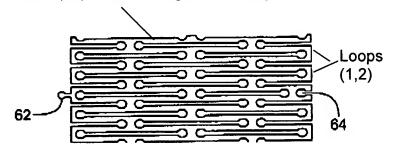
Art Unit: 3731

18. Regarding Claim 3, Chew et al. discloses the medical device as stated above further including at least one receptacle configured as a space between adjacent longitudinal struts that defines a cavity for the elongate member and protrusion member (Fig 5B, "64").

19. Regarding Claim 4, Chew et al. discloses the medical device as stated above wherein the cavity and the mating protrusion have a substantially oval shape (Fig 5C, "64" and "62").

20. Regarding Claim 7, Chew et al. discloses the medical device as stated in paragraph 1, wherein the plurality of struts and the plurality of loops form a substantially S-shaped configuration (Fig 5B). The following illustration is taken from Fig 5B of Chew et al. and has a strut and loop labeled.

Strut (54) runs the length of the segment



Claim Rejections - 35 USC § 103

21. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

Art Unit: 3731

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

- 22. Claims 5, 6, 8, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alt et al. in view of Davila et al. (U.S. 6,863,685). In regards to claims 5 and 6, Alt et al. describes the invention substantially as described above, further disclosing that the medical device is made of a material that renders the stent self-expandable (see claim 7). Alt et al. fails to disclose that the material is a superelastic alloy.
- 23. Davila et al. discloses that it is old and well known in the art to make a stent from a superelastic alloy such as Nitinol. Davila et al. further discloses that it is old and well known in the art to construct a self-expandable stent from an alloy comprising about fifty percent to about sixty percent Nickel and the remainder titanium. Davila et al. states that the superelastic design of the stent makes it crush recoverable which makes it useful as a stent or frame for any number of vascular devices in different applications (col.6, lines 32-45). Therefore, it would have been obvious to one of ordinary skill in the art to modify Alt et al. to include the improvements disclosed by Davila et al. in order to gain the advantages of a medical device that is crush recoverable.
- 24. Regarding claims 8 and 9, Alt et al. discloses the invention substantially as described above. Alt et al. fails to disclose the addition of one or more radiopaque markers.
- 25. Davila et al. discloses that it is old and well known in the art to use radiopaque markers in a stent medical device. Davila et al. further discloses that radiopaque markers ensure proper positioning of the device within a lumen (col. 5, lines 9-11). Also,

Art Unit: 3731

Davila et al. states, the markers may be positioned at other locations on the stent (col. 12, lines 52-53) and markers may be utilized to determine when and if a stent is fully deployed (col. 10, lines 64-65). Therefore, it would have been obvious to one of ordinary skill in the art to modify Alt et al. to include the improvements made obvious by Davila et al. in order to gain the advantage of being able to ensure proper positioning of the device within a lumen. Positioning the markers into the mating protrusion would have been obvious in order to determine when and if each segment of the stent is fully deployed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen Sonnett whose telephone number is 571-272-5576. The examiner can normally be reached on 7:30AM-5PM, Monday-Friday, alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3731

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ANHTUANT. NGUYEN
SUPERVISORY PATENT EXAMINER